



**UNITED STATES DEPARTMENT OF COMMERCE**  
**Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/361,655	07/27/99	LEE	S JHU1220-4

LISA A HAILE PHD  
GRAY CARY WARE & FREIDENRICH LLP  
4365 EXECUTIVE DRIVE SUITE 1600  
SAN DIEGO CA 92121-2189

HM22/0122

EXAMINER

MERTZ, P

ART UNIT

PAPER NUMBER

1646

7

DATE MAILED:

01/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.  
09/361,655

Applicant(s)  
Lee et al.

Examiner  
Prerna Mertz

Group Art Unit  
1646



☒ Responsive to communication(s) filed on Dec 4, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

☒ Claim(s) 15, 16, 18-22, and 44 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 15, 16, 18-22, and 44 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1646

**DETAILED ACTION**

1. Claims 1-14, 23-43 have been canceled previously. Claim 17 has canceled in No.6 (12/4/00). Amended claims 15-16, 18, 22, claims 19-21, and new claim 44 (Paper No. 6, 12/4/00), are under consideration.

2. Receipt of applicant's arguments and amendments filed in Paper No. 6 (12/4/00) is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed in Paper No. 6, 12/4/00:

- (I) the objection to the title of the invention and objection to the specification and
- (ii) the rejection of claims 15-16, 18-22, under 35 U.S.C. § 112, second paragraph.

4. Applicant's arguments filed in Paper No. 6 (12/4/00), have been fully considered but were persuasive in part. The issues remaining, are restated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim rejections-35 U.S.C. § 101/112, first paragraph***

6. Claims 15-16, 18-22, 44, are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

This rejection is maintained for reasons of record set forth at pages 3-5 of the previous Office action (Paper No. 5, 8/29/00).

Art Unit: 1646

Applicants argue that as demonstrated in Example 2 at page 27, GDF-12 is primarily expressed in the liver and that established diagnostics measure changes in proteins found in tissue as indicative of a metabolic or cellular change in the tissue and potentially indicative of a disorder. However, contrary to applicants arguments, the instant protein is at best a liver protein. Applicants assertion that the antibody to GDF-12 can be employed in the claimed method in detection of a liver disorder is not credible utility. There is absolutely no evidence of record or scientific rational to support an association of the claimed invention with a particular liver disorder. A patent is granted for an invention which is useful in "currently available form". To employ a polynucleotide of the instant invention in the diagnosis of a liver disease would first require a practitioner of the art to make the substantial inventive contribution of first discovering a liver disease with which the protein encoded thereby is associated and such an inventive contribution would clearly entail undue experimentation. In the instant case, it is the responsibility of Applicant to disclose a credible utility for the claimed invention and factually unsupported assertions likes those presented in the arguments by Applicants are so incredible on their face that they need not be "proven" wrong.

Therefore, contrary to Applicants arguments, the instant specification does not disclose a single credible, specific or substantial utility for the instant polynucleotides. In conclusion, Applicants arguments with respect to utility of the instant polynucleotides, are found to be non-persuasive.

***Claim Rejections - 35 USC § 112, first paragraph***

7. Claims 15-16, 18-22, 44, are rejected under 35 U.S.C. § 112, first paragraph.

Art Unit: 1646

This rejection is maintained for reasons of record set forth at page 5 of the previous Office action (Paper No. 5, 8/29/00).

Since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Applicants have not demonstrated differential expression of the GDF-12 gene in normal and diseased hepatocytes and therefore Applicants have failed to provide guidance for how to use the instant polynucleotides to be indicative of cellular metabolic changes in liver.

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Advisory Information***

Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Prema Mertz*

Prema Mertz Ph.D.

Primary Examiner

Art Unit 1646

December 21, 2000